General

Guideline Title

Depth of anaesthesia monitors – Bispectral Index (BIS), E-Entropy and Narcotrend-Compact M.

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Depth of anaesthesia monitors â€“ Bispectral Index (BIS), E-Entropy and Narcotrend-Compact M. London (UK): National Institute for Health and Care Excellence (NICE); 2012 Nov. 40 p. (Diagnostics guidance; no. 6).

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The use of electroencephalography (EEG)-based depth of anaesthesia monitors is recommended as an option during any type of general anaesthesia in patients considered at higher risk of adverse outcomes. This includes patients at higher risk of unintended awareness* and patients at higher risk of excessively deep anaesthesia.† The Bispectral Index (BIS) depth of anaesthesia monitor is therefore recommended as an option in these patients.

The use of EEG-based depth of anaesthesia monitors is also recommended as an option in all patients receiving total intravenous anaesthesia. The BIS monitor is therefore recommended as an option in these patients.

Although there is greater uncertainty of clinical benefit for the E-Entropy and Narcotrend-Compact M depth of anaesthesia monitors than for the BIS monitor, the Committee concluded that the E-Entropy and Narcotrend-Compact M monitors are broadly equivalent to BIS. These monitors are therefore recommended as options during any type of general anaesthesia in patients considered at higher risk of adverse outcomes. This includes patients at higher risk of unintended awareness and patients at higher risk of excessively deep anaesthesia. The E-Entropy and Narcotrend-Compact M monitors are also recommended as options in patients receiving total intravenous anaesthesia.‡

Anaesthetists using EEG-based depth of anaesthesia monitors should have appropriate training and experience with these monitors and understand the potential limitations of their use in clinical practice.

*Patients who are considered at higher risk of unintended awareness during general anaesthesia include patients with high opiate or high alcohol use, patients with airway problems, and patients with previous experience of accidental awareness during surgery. The risk of unintended

awareness is also raised by the use of concomitant muscle relaxants. Older patients, patients with comorbidities and those undergoing certain types of surgery are also considered at higher risk of unintended awareness. This is because they are at greater risk of haemodynamic instability during surgery. In these patients, lower levels of anaesthetic are often used to prevent adverse effects on the cardiovascular system and these levels can be inadequate.

†Patients who are considered at higher risk of excessively deep levels of anaesthesia include older patients, patients with liver disease, patients with a high body mass index (BMI), and patients with poor cardiovascular function.

‡Patients receiving total intravenous anaesthesia are not considered at higher risk of adverse outcomes from general anaesthesia than patients receiving inhaled anaesthesia. The use of EEG-based depth of anaesthesia monitors has been recommended in patients receiving total intravenous anaesthesia because it is cost effective and because it is not possible to measure end-tidal anaesthetic concentration in this group.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Any disease or condition requiring surgery using general anaesthesia or total intravenous anaesthesia

Guideline Category

Evaluation

Management

Risk Assessment

Technology Assessment

Clinical Specialty

Anesthesiology

Pediatrics

Surgery

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To determine the clinical effectiveness and cost-effectiveness of 3 depth of anaesthesia monitors (Bispectral Index [BIS], E-Entropy, and

Narcotrend-Compact M), in combination with standard clinical monitoring, in patients receiving general anaesthesia

Target Population

Adults and children receiving any type of general anaesthesia

Interventions and Practices Considered

Electroencephalography (EEG)-based depth of anaesthesia monitoring: Bispectral Index (BIS), E-Entropy and Narcotrend-Compact M monitors

Major Outcomes Considered

- Consumption of anaesthetic agents
- Time to extubation
- Time to discharge from the recovery room
- Probability of awareness during surgery
- Patient distress and other sequelae resulting from awareness during surgery
- Morbidity including postoperative cognitive dysfunction
- Mortality
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an External Assessment Group to perform a systematic literature review on the technology considered in this diagnostics guidance and prepare a Diagnostics Assessment Report (DAR). The DAR for this guidance was prepared by the Southampton Health Technology Assessments Centre (SHTAC), University of Southampton (see the "Availability of Companion Documents" field).

Systematic Review of Patient Outcomes

Identification of Studies

A search strategy was developed for Medline and pilot tested by an experienced information scientist. The Medline strategy (see Appendix 2 in the DAR) was adapted where necessary to the specific vocabulary and rules of other electronic bibliographic databases. Searches were run in the following databases: Ovid Medline; Ovid EMBASE; Centre for Reviews and Dissemination (CRD); Cochrane Central; Cochrane Library (Cochrane Database of Systematic Reviews; Cochrane Central Register of Controlled Trials); Database of Abstracts of Reviews of Effectiveness (DARE); and Health Technology Assessment Database (HTA). For Entropy and Narcotrend the electronic searches were conducted from 1995 (around the time of the introduction of electroencephalography [EEG] technologies) to November 2011 (with an update search performed in February 2012).

Scoping searches indicated that the volume of evidence for Bispectral Index (BIS) was relatively larger than for Narcotrend and Entropy and it

would be beyond the resources available to include all of the BIS studies in the systematic review. During preliminary scoping searches the Assessment Group identified a recent Cochrane systematic review of BIS that had similar study eligibility criteria to their review (with the exception that it did not include studies of children). The Assessment Group therefore based their review of BIS upon a Cochrane systematic review, which contained 31 randomised controlled trials (RCTs) of BIS. The most recent date of literature searching in the Cochrane review was May 2009. The Assessment Group therefore searched from the beginning of 2009 to November 2011 for studies of BIS (and then updated in February 2012) (see Section 4.1.4 in the DAR for further information about how results from the Cochrane review are integrated into the current review.) For studies of E-entropy and Narcotrend the searches were run from 1995 to November 2011 (and then updated in February 2012).

In addition to the searches of electronic bibliographic databases, the following sources were searched to identify potentially relevant studies:

- Contact with experts in the field (identified by NICE as part of the consultation process)
- Bibliographic lists of potentially relevant studies on BIS, Entropy and Narcotrend as supplied by the device manufacturers (via NICE)
- Reference lists of included studies
- Databases of research in progress, searched on 07 December 2011: UK Clinical Research Network (UKCRN); Current Controlled Trials; clinicaltrials.gov; National Institute for Health Research (NIHR)-Clinical Research Network Portfolio; WHO ICTRP (World Health Organization International Clinical Trials Registry Platform)

The titles and abstracts of studies identified from these searches were imported into a Reference Manager bibliographic database. All titles and abstracts in this database were assessed against the inclusion/exclusion criteria (see below). Bibliographic records that clearly did not meet any of the inclusion criteria, or met at least one of the exclusion criteria, were excluded from further consideration. For each bibliographic record that met all of the inclusion criteria, or was of unclear relevance, a full-text version was obtained and assessed against the inclusion/exclusion criteria. Full-text records that clearly did not meet all of the inclusion criteria were excluded from further consideration, and the reasons for their exclusion were noted.

Both the title and abstract selection step and the full text selection step were conducted independently by two reviewers. After screening the bibliographic records, the reviewers compared their selection results. All initial differences in opinion were resolved through discussion, without needing to involve a third reviewer.

Inclusion/Exclusion Criteria

Only articles published in the English language were included. Abstracts that had no corresponding full-text record (e.g., conference abstracts) were excluded unless they met two criteria: they were published in 2010 or later and they provided sufficient details to allow appraisal of the methodology and the assessment of results to be undertaken.

The inclusion/exclusion criteria were provided to each reviewer as a standard list against which each title/abstract or full-text record could be readily assessed (see Appendix 3 in the DAR). In addition to the language and publication type restrictions, the following selection criteria were applied:

Population

- Included: patients who received general anaesthesia for surgery, including adults and children (over the age of two years) in whom the technology is licensed.
- Excluded: studies of patients receiving sedation in intensive care or high dependency units; studies in healthy volunteers; studies in non-surgical anaesthesia.

Diagnostic Technologies

Included: E-Entropy, BIS, Narcotrend

Comparators

Included: Standard clinical monitoring for monitoring delivery of anaesthesia, including one or more of the following clinical markers: end-tidal anaesthetic gas concentrations (for inhaled anaesthesia); pulse measurement; heart rhythm; blood pressure; lacrimation, and sweating.

Outcomes

Studies were included if at least one of the following outcomes was reported:

- Probability of intraoperative awareness
- Patient distress and other sequelae resulting from intraoperative awareness

- Recovery status (e.g., Aldrete scoring system)
- Time to emergence from anaesthesia
- Time to extubation
- Time to discharge from the recovery room
- Consumption of anaesthetic agents
- Morbidity and mortality including postoperative cognitive dysfunction (POCD) from anaesthetic agents, pain-relieving drugs, antibiotics, anti-sickness drugs and muscle relaxants.

Study Design

Limited to prospective controlled trials (once studies had been included in the systematic review, priority was given to RCTs unless no RCT evidence for relevant parameters was available in which case non-RCT data would be considered). Systematic reviews that met the inclusion criteria were retrieved in order to check their reference lists for potentially relevant studies but were not themselves evaluated (except for the Cochrane systematic review of BIS technologies).

Systematic Review of Cost-effectiveness

Identification of Studies

A comprehensive search strategy was developed, tested and refined by an experienced information scientist to identify studies of the cost-effectiveness of depth of anaesthesia monitoring. The Medline search strategy is provided in Appendix 2 in the DAR.

A total of six electronic resources were searched. Searches were from database inception to November 2011 (an update search was done in February 2012). The following electronic databases were searched: Medline (Ovid); Medline In-Process (MEIP); EMBASE; The Cochrane Library including Central Register of Controlled Trials (CENTRAL) and Cochrane Database of Systematic Reviews (CDSR); Centre for Reviews and Dissemination (CRD) including Health Technology Assessment Database, Database of Abstracts of Reviews of Effects (DARE) and National Health Service Economic Evaluation Database (NHS EED); ECONLIT. Bibliographies of retrieved articles were checked for any additional references, and the expert advisory group were contacted to identify additional published and unpublished studies.

Inclusion/Exclusion Criteria

Studies were selected for inclusion in the systematic review of cost-effectiveness through a two-stage process using predefined and explicit criteria. The full literature search results were independently screened by two reviewers to identify all citations that possibly met the inclusion criteria using criteria in the table below.

Table. Inclusion/Exclusion Criteria for Screening Titles and Abstracts

Criterion	
Population	Patients receiving general anaesthetic for surgery, including adults and children in whom the technology is licensed
Interventions	Any depth of anaesthesia monitoring device
Design	Economic evaluation (cost consequence analysis, cost effectiveness analysis, cost utility analysis, cost benefit analysis)
Outcomes	Cost per patient, cost per episode of intraoperative awareness or cost per quality-adjusted life year (QALY)
Other	Exclude non-English language Exclude conference abstracts

Full papers of relevant studies were retrieved and assessed independently by two reviewers using a standardised eligibility form, using the same inclusion/exclusion criteria, except that only studies with standard treatment specified as "no depth of anaesthesia monitor" were included. Studies reporting other outcomes (one or more of probability of intraoperative awareness, consumption of anaesthetic agents, post-operative morbidity or mortality, health-related quality of life) were not included in the review, but were retained to inform the development and population of the decision analytic model.

Number of Source Documents

Systematic Review of Patient Outcomes

In total, 776 bibliographic records were identified from electronic bibliographic databases and reference lists provided by the manufacturers of the Bispectral Index (BIS), Entropy and Narcotrend monitors (see Figure 1 in the Diagnostics Assessment Report [DAR] [see the "Availability of Companion Documents" field]).

Of these 776 records, 741 were excluded based on information provided in the title and/or abstract. Full-text publications were obtained and assessed for the remaining 35 records, of which 10 were found on further scrutiny to not meet the inclusion criteria. Reasons for excluding the 10 full-text records were that they were not randomised controlled trials (RCTs) (five publications), they included an inappropriate or unclear comparator group (four publications) and, in one case, the publication was retracted by the journal (see Appendix 4 in the DAR).

The remaining 25 full-text publications reported 25 studies which were eligible for inclusion in the systematic review. Four of the 25 RCTs were identified by update searches in February 2012, all evaluating BIS. Due to finite time and resources the largest of these were prioritised for inclusion in the review (a trial of around 5000 patients, specifically designed to assess intraoperative awareness). The other three were smaller trials (80 patients, 40 patients, and 20 patients, respectively) and their inclusion in the review was unlikely to change the findings. In summary, a total of 22 RCTs were included in this systematic review.

Systematic Review of Cost-effectiveness

- A total of 134 potentially relevant references were identified in the cost effectiveness searches. Of these, the full text of 14 papers was retrieved and one study met all of the *a priori* inclusion criteria. A summary of the selection process and the reasons for exclusion are presented in Figure 5 in the DAR; a list of excluded studies can be found in Appendix 7 in the DAR (see the "Availability of Companion Documents" field).
- A decision analytic model was submitted by the Assessment Group.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an External Assessment Group to perform a systematic literature review on the technology considered in this diagnostics guidance and prepare a Diagnostics Assessment Report (DAR). The DAR for this guidance was prepared by the Southampton Health Technology Assessments Centre (SHTAC), University of Southampton (see the "Availability of Companion Documents" field).

Systematic Review of Patient Outcomes

Data Extraction and Critical Appraisal Methods

A standardised data extraction and quality appraisal template (see Appendix 5 in the DAR) was used to extract information on the relevant study characteristics for assessing the impact of the interventions on the outcomes and for assessing study quality. Study quality assessment criteria included: Cochrane Collaboration Risk of Bias criteria as specified in the review protocol; methods of data analysis, including the statistical tests used and whether studies were powered statistically to detect differences in outcomes between intervention and comparator groups; participant

attrition; generalisability of the studies; and conflict of interests. Criteria for the critical appraisal of non-randomised and observational studies were specified in the protocol but were not required, as all the included studies were randomised controlled trials (RCTs).

The data extraction and critical appraisal template was completed for each study included in the systematic review by one reviewer and was checked by a second reviewer. All initial discrepancies between the reviewers were resolved by discussion, without needing to involve a third reviewer.

Method of Data Synthesis

Analyses of the three monitoring devices are presented in respective separate sub-sections of the DAR. For each device a narrative synthesis was conducted, with characteristics of the included trials, and their outcomes, described in the text and tabulated.

The analysis of Bispectral Index (BIS) was based on trials included in an existing Cochrane review of BIS and supplemented by trials identified and included in the current systematic review. For each BIS outcome measure the Assessment Group presents a narrative synthesis of the studies identified in the current systematic review, in addition to the pooled meta-analysis estimates from the Cochrane review. Where possible the Cochrane meta-analyses for BIS have been updated with trials identified in the current review. However, the Cochrane BIS review only included trials of adults, and it was not considered appropriate to combine trials of children identified in the Assessment Group's searches with the existing adult trials. Cochrane Review Manager version 5.1.6 was used to conduct the meta-analyses.

Systematic Review of Cost-effectiveness

Data Extraction and Critical Appraisal Methods

Data were extracted by one reviewer using a standard data extraction form (see Appendix 6 in the DAR) and checked by a second reviewer. At each stage, any disagreements between reviewers were resolved by consensus.

The quality of the included economic evaluations was assessed using a critical appraisal checklist based upon that proposed by Drummond and colleagues and Philips and colleagues (see Appendix 6 in the DAR).

Method of Data Synthesis

Studies of cost-effectiveness were synthesised through a narrative review with tabulation of results of included studies, where appropriate.

Economic Evaluation

A decision analytic model was developed to assess the cost-effectiveness of depth of anaesthesia monitoring, compared with standard clinical monitoring, adopting the perspective of the UK National Health Service (NHS). Separate analyses are presented for each of the included technologies, compared with standard clinical monitoring – the included technologies are not compared with each other.

The scope issued by NICE identified a number of health outcomes, including morbidity and mortality from anaesthetic agents, pain relieving drugs, antibiotics, anti-sickness drugs and muscle relaxants as well as patient discomfort and sequelae resulting from intraoperative awareness. The model was developed to allow for the inclusion of these outcomes, if suitable data on baseline values and the effect of depth of anaesthesia monitoring on these outcomes was identified in the systematic review of patient outcomes. Outcomes in the model are expressed as quality-adjusted life years (QALYs). The model evaluates costs from the perspective of the NHS and personal social services. Costs are expressed in UK sterling (pounds, £) at a 2011 price base. Both costs and outcomes are discounted using a 3.5% annual discount rate, in line with current guidance.

Modelling Approach and Model Structure

The model developed for this assessment was a simple decision tree, which accounted for patients' risk of experiencing short-term anaesthetic-related complications (such as post-operative nausea and vomiting [PONV]) and more serious complications that may be associated with risk of morbidity or mortality. These were included, in addition to a risk of experiencing intraoperative awareness (see Figure 6 in the DAR).

Each of the short-term anaesthetic-related complications could be associated with additional treatment costs (such as anti-emetic medication for patients experiencing PONV, while for patients experiencing post-operative cognitive dysfunction [POCD] there may be in-hospital costs of managing the condition, additional days of hospital stay and, for longer-term cases, additional costs of managing the condition following discharge). No direct cost consequences for intraoperative awareness are included in the model. However it is assumed that a proportion of patients who experience awareness will suffer psychological symptoms arising from the awareness episode and that a proportion of those will develop post-traumatic stress disorder (PTSD) and may seek treatment.

See Sections 4 and 5 in the DAR for additional information.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Developing Recommendations

After reviewing the evidence the Diagnostic Advisory Committee (DAC) agrees draft recommendations on the use of the technology in the National Health Service (NHS) in England. When formulating these recommendations, the Committee has discretion to consider those factors it believes are most appropriate to the evaluation. In doing so, the Committee has regard to any relevant provisions of the National Institute for Health and Care Excellence's (NICE's) Directions, set out by the Secretary of State for Health, and legislation on human rights, discrimination and equality. In undertaking evaluations of healthcare technologies, NICE takes into account the broad balance of clinical benefits and costs, the degree of clinical need of patients under consideration, any guidance issued to the NHS by the Secretary of State that is specifically drawn to the attention of NICE by the Secretary of State, and any guidance issued by the Secretary of State, and the potential for long-term benefits to the NHS of innovation.

The Committee takes into account advice from NICE on the approach it should take to making scientific and social value judgements. Advice on social value judgements is informed in part by the work of NICE's Citizens Council.

The Committee takes into account how its judgements have a bearing on distributive justice or legal requirements in relation to human rights, discrimination and equality. Such characteristics include, but are not confined to: race, gender, disability, religion or belief, sexual orientation, gender reassignment and pregnancy or maternity.

The Committee considers the application of other Board-approved NICE methods policies, such as the supplementary guidance on discounting and the end-of-life criteria, if they are relevant to the evaluation.

Because the Programme often evaluates new technologies that have a thin evidence base, in formulating its recommendations the Committee balances the quality and quantity of evidence with the expected value of the technology to the NHS and the public.

The credibility of the guidance produced by NICE depends on the transparency of the DAC's decision-making process. It is crucial that the DAC's decisions are explained clearly, and that the contributions of registered stakeholders and the views of members of the public are considered. The reasoning behind the Committee's recommendations is explained, with reference to the factors that have been taken into account.

The language and style used in the documents produced by the Committee are governed by the following principles:

- Clarity is essential in explaining how the DAC has come to its conclusions.
- The text of the documents does not need to reiterate all the factual information that can be found in the information published alongside the guidance. This needs careful judgement so that enough information and justification is given in the recommendations to enable the reader to understand what evidence the DAC considered and, if appropriate, who provided that evidence.

The Committee may take into account factors that may provide benefits to the NHS or the population, such as patient convenience. It may also consider costs and other positive or negative impacts on the NHS that may not be captured in the reference-case cost analysis, such as improved processes.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A systematic review of the evidence on cost-effectiveness for the 3 technologies was undertaken by the External Assessment Group. One study was identified that evaluated the cost effectiveness of standard clinical monitoring in combination with Bispectral Index (BIS) monitoring compared with standard clinical monitoring alone. The cost per patient of BIS monitoring included the cost of the sensors and the monitor. An incidence of awareness during surgery of 0.04% was used for standard clinical monitoring in combination with BIS monitoring and 0.18% was used for standard clinical monitoring alone. The study concluded that the addition of BIS monitoring to standard clinical monitoring was not cost effective.

However, the study did not include health-related quality of life and its methodology was of uncertain quality.

No studies were identified that included E-Entropy or Narcotrend-Compact M monitoring and met the inclusion criteria for the systematic review on cost-effectiveness.

An economic model was developed by the External Assessment Group to assess the cost-effectiveness of using a monitor to assess the depth of anaesthesia plus standard clinical monitoring compared with standard clinical monitoring alone. The model evaluated costs from the perspective of the National Health Service (NHS) and personal social services. Outcomes were expressed as quality-adjusted life years (QALYs). Both costs and outcomes were discounted using a 3.5% annual discount rate. Separate economic analyses were conducted for each of the 3 technologies. No analyses were conducted to directly compare the technologies.

A decision tree model was developed to evaluate the outcomes and costs resulting from the use of depth of anaesthesia monitors as opposed to standard clinical monitoring alone. Three separate models were developed, 1 for each monitoring system. However, the model structures were the same, with only the values for the parameters varying. The models used different values for the risks associated with standard clinical monitoring (without a depth of anaesthesia monitor) corresponding to the results in the respective trials.

Patients at High Risk of Adverse Outcomes from Anaesthesia Receiving Total Intravenous Anaesthesia

The base-case analysis for patients at high risk of adverse outcomes from anaesthesia receiving total intravenous anaesthesia resulted in incremental cost-effectiveness ratios (ICERs) of £21,940, £14,421 and £5681 per QALY gained for BIS, E-Entropy and Narcotrend-Compact M monitoring respectively, compared with standard clinical monitoring alone.

Patients at General Risk of Adverse Outcomes from Anaesthesia Receiving Total Intravenous Anaesthesia

The base-case analysis for patients at general risk of adverse outcomes from anaesthesia receiving total intravenous anaesthesia resulted in ICERs of £33,478 and £31,131 per QALY gained for the use of BIS and E-Entropy monitors respectively, compared with standard clinical monitoring alone. Monitoring with the Narcotrend-Compact M monitor dominated standard clinical monitoring in this population (that is, it was more effective and less costly than standard clinical monitoring).

Patients at High Risk of Adverse Outcomes from Anaesthesia Receiving Either Intravenous or Inhaled Anaesthesia

The base-case analysis for patients at high risk of adverse outcomes from anaesthesia receiving intravenous or inhaled anaesthesia resulted in ICERs of £29,118, £19,367 and £8,033 per QALY gained for the use of BIS, E-Entropy and Narcotrend-Compact M monitors respectively, compared with standard clinical monitoring alone.

Patients at General Risk of Adverse Outcomes from Anaesthesia Receiving Either Intravenous or Inhaled Anaesthesia

The base-case analysis for patients at general risk of adverse outcomes from anaesthesia receiving intravenous or inhaled anaesthesia resulted in ICERs of £47,882 and £19,000 per QALY gained for the use of BIS and E-Entropy monitors respectively, compared with standard clinical monitoring alone. Monitoring with the Narcotrend-Compact M monitor dominated standard clinical monitoring in this population (that is, it was more effective and less costly than standard clinical monitoring).

Considerations

Notwithstanding the uncertainty in the evidence base, the Committee considered that depth of anaesthesia monitoring is most likely to be cost effective and of clinical benefit in patients receiving total intravenous anaesthesia and in patients considered at higher risk of unintended awareness or of excessively deep levels of general anaesthesia.

Refer to Sections 5 and 6 in the original guideline document for additional information on the cost-effectiveness analysis and Committee considerations.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

The National Institute for Health and Care Excellence (NICE) sends the Diagnostics Assessment Report (DAR), with any confidential material

removed, to registered stakeholders for comment. Stakeholders have 10 working days to return comments. Models supporting the DAR are made available to registered stakeholders on request during this period.

NICE presents anonymised registered stakeholder comments on the DAR, along with any responses from NICE or the External Assessment Group (EAG), to the Committee and later publishes these comments on its website.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Diagnostics Advisory Committee considered clinical and cost-effectiveness evidence from a systematic review of depth-of-anaesthesia monitors (E-Entropy, Bispectral Index [BIS] and Narcotrend) performed by an External Assessment Group.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Measuring a patient's response to anaesthesia is important clinically because individual variation in response to anaesthetics can occasionally lead to inadequate or excessively deep levels of anaesthesia. An inadequate level of anaesthesia can result in patient awareness during surgery, which can cause post-traumatic stress disorder in some patients. Conversely, an excessively deep level of anaesthesia can result in prolonged recovery and has been linked to an increased risk of postoperative adverse outcomes, including myocardial infarction, stroke and cognitive dysfunction in older patients.

Potential Harms

All electroencephalographic (EEG) monitoring is subject to contamination by artefacts generated either by the patient (e.g., by eye movements, muscle activity) or from external source (poor skin contact, mains or power line interference, electrocautery). With the Bispectral Index (BIS) system most artefacts present as elevated BIS values and the recommended strategy from the manufacturer for an unexpected elevated BIS value is prompt patient assessment, confirmation of anaesthetic dosing and delivery and consideration of artefacts. Narcotrend is equipped with artefact detection algorithms to exclude segments contaminated with artefact from further analysis. If too many artefacts are detected, no classification result will be output and only raw EEG will be visible on screen.

Qualifying Statements

Qualifying Statements

- This guidance represents the view of the National Institute for Health and Care Excellence (NICE), which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

The National Institute for Health and Care Excellence (NICE) has developed a tool to help organisations put this guidance into practice (listed below) (see also the "Availability of Companion Documents" field).

- A costing statement explaining the resource impact of this guidance.

Implementation Tools

Mobile Device Resources

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Safety

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Depth of anaesthesia monitors â€“ Bispectral Index (BIS), E-Entropy and Narcotrend-Compact M. London (UK): National Institute for Health and Care Excellence (NICE); 2012 Nov. 40 p. (Diagnostics guidance; no. 6).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Nov

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

Guideline Committee

Diagnostics Advisory Committee

Composition of Group That Authored the Guideline

Standing Committee Members: Dr Trevor Cole, Consultant Clinical Geneticist, Birmingham Women's Hospital Foundation Trust; Dr Paul Collinson, Consultant Chemical Pathologist, St George's Hospital; Professor Ian Cree, Director of Efficacy and Mechanisms Programme, NIHR Evaluation, Trials and Studies Coordinating Centre, University of Southampton; Dr Erika Denton, National Clinical Director for Imaging, Department of Health; Dr Simon Fleming, Consultant in Clinical Biochemistry and Metabolic Medicine, Royal Cornwall Hospital; Professor Elizabeth (Lisa) Hall, Professor of Analytical Biotechnology, Institute of Biotechnology, Department of Chemical Engineering and Biotechnology, University of Cambridge; Professor Chris Hyde, Professor of Public Health and Clinical Epidemiology, Peninsula College of Medicine and Dentistry; Professor Noor Kalsheker, Professor of Clinical Chemistry, Molecular Medical Sciences, University of Nottingham; Dr Mark Kroese, Consultant in Public Health Medicine, PHG Foundation and UK Genetic Testing Network; Professor Adrian Newland (*Chair*), Consultant Haematologist, Barts and the London NHS Trust; Dr Richard Nicholas, Consultant Neurologist, Heatherwood and Wexham Park Hospital, Imperial Healthcare Trust; Ms Margaret Ogden, Lay member; Dr Diego Ossa, Global Head, Health Economic and Outcomes Research, Novartis Molecular Diagnostics; Mr Stuart Saw, Director of Finance and Procurement, Tower Hamlets Primary Care Trust; Professor Mark Sculpher, Professor of Health Economics, Centre for Health Economics, University of York; Dr Steve Thomas, Senior Lecturer and Consultant Radiologist, University of Sheffield; Mr Paul Weinberger, CEO, Diasolve Ltd, London; Mr Christopher Wiltsher, Lay member

Specialist Committee Members: Dr John Andrzejowski, Consultant in Anaesthesia and Neurointensive Care, Royal Hallamshire Hospital, Sheffield; Professor Anthony Fisher, Consultant Clinical Scientist, Royal Liverpool and Broadgreen University Hospitals; Mr John Hitchman, Lay member; Dr David Smith, Consultant/Senior Lecturer in Cardiac Anaesthesia (A+B), Southampton General Hospital; Dr Andrew Smith, Consultant Anaesthetist, Royal Lancaster Infirmary; Professor Michael Wang, Professor of Clinical Psychology/Honorary Consultant Clinical Psychologist, University of Leicester

Financial Disclosures/Conflicts of Interest

Committee members are required to submit a declaration of interests on appointment, in every year of their tenure, and at each Committee meeting, in line with the National Institute for Health and Care Excellence's (NICE's) code of practice for declaring and dealing with conflicts of interest.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available

for download as a Kindle or EPUB ebook from the NICE Web site .

Availability of Companion Documents

The following are available:

- Shepherd J, Jones J, Frampton G, Bryant J, Baxter L, Cooper K. Depth of anaesthesia monitoring (E-Entropy, Bispectral Index and Narcotrend). Diagnostics assessment report. Southampton (UK): Southampton Health Technology Assessments Centre (SHTAC), University of Southampton; 2012 Apr. 343 p. Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .
- Addendum to the diagnostic assessment report on depth of anaesthesia monitoring (E-Entropy, Bispectral Index and Narcotrend). Southampton (UK): Southampton Health Technology Assessments Centre (SHTAC), University of Southampton; 2012 May. 7 p. Electronic copies: Available from the NICE Web site .
- Electroencephalography (EEG)-based depth of anasethesia monitors-Bispectral Index (BIS), E-Entropy and Narcotrend-Compact M. Costing statement. London (UK): National Institute for Health and Care Excellence (NICE); 2012 Nov. 9 p. (Diagnostics guidance; no. 6). Electronic copies: Available from the NICE Web site .
- Depth of anaesthesia monitors (E-Entropy, BIS and Narcotrend). Podcast with Dr David Smith. London (UK): National Institute for Health and Care Excellence (NICE); 2012 Nov. (Diagnostics guidance; no. 6). Electronic copies: Available from the NICE Web site .
- Diagnostics Assessment Programme manual. London (UK): National Institute for Health and Care Excellence; 2011 Dec. 130 p. Electronic copies: Available from the NICE Web site .

Patient Resources

The following is available:

- Depth of anaesthesia monitors – Bispectral Index (BIS), E-Entropy and Narcotrend-Compact M. Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2012 Nov. (Diagnostics guidance; no. 6). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on January 2, 2015.

The National Institute for Health and Care Excellence (NICE) has granted the National Guideline Clearinghouse (NGC) permission to include summaries of their Diagnostics guidance with the intention of disseminating and facilitating the implementation of that guidance. NICE has not verified this content to confirm that it accurately reflects the original NICE guidance and therefore no guarantees are given by NICE in this regard. All NICE diagnostics guidance is prepared in relation to the National Health Service in England and Wales. NICE has not been involved in the development or adaptation of NICE guidance for use in any other country. The full versions of all NICE guidance can be found at www.nice.org.uk .

Copyright Statement

Disclaimer

NGC Disclaimer

The National Guideline Clearinghouseâ„¢ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion-criteria.aspx.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.